

Remarks/Arguments

Applicants respectfully traverse the rejections presented in the Office Action. The original claims, Claims 1-20, remain pending in the application. Applicants respectfully request reconsideration of the pending claims, in view of the comments below.

Double Patenting

The Examiner provisionally rejected Claims 1-3 and 18 based on the judicially-created doctrine of obviousness-type double patenting in view of Claims 1-3 and 17 of co-pending Application No. 10/607,962. As this is merely a *provisional* rejection, Applicants are not required to take any action in response at the present time.

If co-pending Application No. 10/607,962 should be issued prior to the present application, Applicants will consider filing a terminal disclaimer to address the double patenting issue. However, Applicants take no position at this time as to whether the claims of the present application and those of co-pending Application No. 10/607,962 might, at some future time, present an actual double patenting issue.

Claim Rejections - 35 U.S.C. § 103

The Examiner rejected Claims 1-20 under 35 U.S.C. § 103(a) as being unpatentable over Nordling (U.S. Patent No. 4,441,498) in view of Schulman et al. (U.S. Patent 5,193,539). Applicants respectfully traverse this rejection.

Independent Claims 1, 12, and 18 include, *inter alia*, a limitation which is not shown, taught, or suggested in Nordling. Applicants submit that the limitation "*a hermetically-sealed housing having a length no greater than about 27 mm and cross-sectional dimensions no greater than about 3.3 mm*" is not shown, taught or suggested in Nordling. The Examiner agrees with this assessment, and has stated that "Nordling fails to teach the dimensions of the housing". Recognizing this deficiency in the teachings of Nordling, the Examiner has combined the teachings of Nordling with the teachings of Schulman et al. to obtain the missing element relating to the size of the hermetically-sealed housing. Applicants' respectfully submit that

making such a combination is improper because a person of ordinary skill in the art would *not* be prompted to combine the teachings of Nordling with the teachings of Schulman et al. to obtain the claimed invention as a whole without the benefit of hindsight, as explained below.

"The requirement *at the time the invention was made* is to avoid impermissible hindsight." (Emphasis added.) MPEP § 2141.01. In addition, "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." (Emphasis in original.) MPEP § 2143.01. Nordling does not teach, or suggest, that the internal components, e.g., planer receiver coil assembly **14**, lithium iodide battery **16**, and pulse generator circuitry **18**, which are housed within the titanium housing or cannister **12**, are designed to fit in a housing having a length no greater than about 27 mm and cross-sectional dimensions no greater than about 3.3 mm. To read such a teaching into the combined teachings of Nordling and Schulman et al. references is to apply hindsight, because there is *nothing* in Nordling that teaches or suggests the concept of manufacturing or using such a small-sized housing, as described in Applicants' claimed invention. For example, Nordling teaches that in a preferred embodiment, battery **16** is a Model 7905, 1.7AH lithium iodine battery and has a shape which generally conforms to the lower portion of the interior of housing **12**. See, e.g., Col. 4, lines 2-7. Such battery cannot fit into a housing having a length no greater than about 27 mm and cross-sectional dimensions no greater than about 3.3 mm. Further, Nordling teaches using the pulse generator **10**, as a pacemaker. See e.g., Col 3, lines 13-14; Col. 4, lines 65-66; Col. 5, lines 10-13; Col. 7, lines 10-15; Col. 7, lines 50-54; and Col. 8, lines 4-5. Thus, the teachings of Nordling would be inefficient for nerve stimulation using a microstimulator having a hermetically-sealed housing sized per Applicants' claimed invention, since the pacemaker components, such as the output circuit **118** which provides the needed pulse energy to stimulate heart **90**, obtains its power source from a battery which is sized to fit in a housing much larger than the housing described in Applicants' claimed invention. Nordling also teaches a pacemaker having an output circuit **118** which generates a 5-volt pulse that is transmitted via electrode **100** to heart **90** for stimulation. See Col 7, lines 50-54.

Applicants' teach an implantable microstimulator, which includes an electronic module having a hermetically-sealed housing with a length no greater than about 27 mm and cross-sectional dimensions no greater than about 3.3 mm. Such housing encloses, *inter alia*, a

processor and other electronic circuitry that allow the microstimulator to generate stimulating pulses that are applied to a patient through electrodes 22 and 24 in accordance with a program stored in programmable memory located within the electronic subassembly 14. See page 18, paragraph [0087]. The processor and electronic circuitry obtain operating power from a self-contained power source means, e.g. a primary battery, a rechargeable battery, a super capacitor, a nuclear battery, a mechanical resonator, an infrared collector, a thermally-powered energy source, a flexural powered energy source, a bioenergy power source, a fuel cell, a bioelectrical cell, and an osmotic pressure pump; which power source means is contained within the hermetically-sealed housing having a length no greater than about 27 mm and cross-sectional dimensions no greater than about 3.3 mm. See, e.g., paragraphs [0015], [0016], [0054] - [0067], and [0085].

Hence, it is respectfully submitted that the combined references of Nordling and Schulman et al. do not teach or suggest an implantable electronic module having, *inter alia*, a hermetically-sealed housing having a length no greater than about 27 mm and cross-sectional dimensions no greater than about 3.3 mm, nor an implantable neural stimulator module having, *inter alia*, a housing with the same dimensions. Rather, as pointed out above, Nordling teaches an implantable programmable ventricular pulse generator which provides electrical pulses to heart 90 of a patient. See, Col. 7, lines 10-13. As known in the pacemaker industry, the components of such pulse generators are enclosed in a housing having dimensions which are much larger than a hermetically-sealed housing described in the present application.

As stated above, Applicants' respectfully submit that a person of ordinary skill in the art would not be prompted to combine the teachings of Nordling with the teachings of Schulman et al. without the benefit of hindsight. Even if all of the elements of Applicants' claimed invention are disclosed in Nordling in view of Schulman et al., the claimed invention as a whole cannot be said to be obvious unless there is a reasonable expectation of success for combining the teachings of the references. MPEP 2143 states: "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or

references when combined) must teach or suggest all the claim limitations." There is no such reasonable expectation of success, because the internal components of the pulse generator at the time Nordling's invention was made could not possibly fit in a hermetically-sealed housing having a length no greater than about 27 mm and cross-sectional dimensions no greater than about 3.3 mm. Applicants' submit that a *prima facie* case of obviousness has not been established since, in addition to the reasons stated earlier, one of skill in the art would not have a reasonable expectation of successfully fitting the components of Nordling into the small housing of Schulman et al. Thus, independent Claims 1, 12, and 18 should now be in condition for allowance.


Further, since Claims 2-11; Claims 13-17; and Claims 19-20 are dependent claims that depend from independent Claims 1, 12, and 18 respectively, and for this reason alone (although not necessarily the only reason) they should be allowable for the same reasons that Claims 1, 12, and 18 are allowable.

Conclusion

In view of the foregoing, it is respectfully submitted that the rejections should be withdrawn and original Claims 1-20 remain pending in the application. An indication of allowability of Claims 1-20 at an early date is thus earnestly solicited.

The Examiner is invited to telephone the undersigned, Victoria A. Poissant, should any issues remain after consideration and entry of this response, in order to permit early resolution of such issues.

Respectfully Submitted,


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